Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Immersive 360-Degree Virtual Reality Simulator for Preparing Women for Vaginal Birth: Development and Pilot Study

Protocol summary

Study aim

The primary objective of this study is to design, develop, and conduct a preliminary evaluation of a virtual reality simulator based on 360-degree videos

Design

Pilot randomized controlled trial with two parallel groups including an intervention group (360-degree virtual reality) and a control group (routine face-to-face education) in 24 pregnant women (12 per group). Randomization will be performed using block randomization with allocation concealment. The study is single-center.

Settings and conduct

The study will be conducted at Taleghani Hospital, Tabriz, Iran. Pregnant women will be recruited via convenience sampling after informed consent.

Participants/Inclusion and exclusion criteria

Pregnant women attending Taleghani Hospital, Tabriz, will be recruited by convenience sampling after informed consent. Inclusion: singleton pregnancy, 20–36 weeks, age 18–45, residence in Tabriz area, literacy in Persian, access to smartphone and internet, and willingness to participate. Exclusion: high-risk pregnancy, severe fear of childbirth (WDEQA >85), major medical or psychiatric disorders, intolerance to virtual reality, or withdrawal.

Intervention groups

Participants will be randomly assigned to two parallel groups. The intervention group will receive 360-degree virtual reality-based childbirth education including breathing, relaxation, labor positions, pain management, and partner support, with optional online access. The control group will receive routine face-to-face childbirth education based on national guidelines.

Main outcome variables

Fear of childbirth; childbirth self efficacy; perceived presence in virtual reality; system usability and user experience; physical preparedness for childbirth skills; feasibility and acceptability of the VR intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220926056046N8**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **prospective**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date

2026-08-29, 1405/06/07

Registrant information

Name

Solmaz Ghanbari Homaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3524 5181

Email address

homayisolmaz@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-20, 1405/07/28

Expected recruitment end date

2027-02-08, 1405/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immersive 360-Degree Virtual Reality Simulator for Preparing Women for Vaginal Birth: Development and Pilot Study

Public title

Development and Initial Evaluation of a 360-Degree Virtual Reality Simulator for Preparing Pregnant Women for Vaginal Birth

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with singleton pregnancy Gestational age between 20 and 36 weeks Maternal age between 18 and 45 years Residence in Tabriz or nearby areas Minimum literacy (ability to read and write Persian) to complete questionnaires and use simulator content Willingness to participate and signing written informed consent No history of epilepsy or uncontrolled seizure disorders No severe dizziness, vestibular disorders, or serious visual/hearing impairment interfering with VR use No previous severe intolerance to virtual reality No severe psychiatric disorders (including psychosis, active bipolar disorder, or severe depression) based on self-report/medical history No simultaneous participation in similar educational programs or other interventional studies Access to internet Access to a smartphone Adequate visual ability for VR use (self-reported; no visual problems interfering with depth perception)

Exclusion criteria:

High-risk pregnancy including severe preeclampsia or gestational hypertension Uncontrolled gestational diabetes Vaginal bleeding during pregnancy Intrauterine growth restriction History or evidence of preterm labor in the current pregnancy Severe fear of childbirth (W-DEQ-A score >85) Severe intolerance to VR during the first session (severe dizziness, uncontrollable nausea, severe headache, seizure-like symptoms) Development of any medical condition during the study making participation unsafe Withdrawal of consent

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible pregnant women will be randomized individually into either the intervention group or the control group with a 1:1 allocation ratio. Randomization will be performed using block randomization with variable block sizes of four and six in order to maintain balance between groups during the recruitment period. The unit of randomization will be the individual participant. The random allocation sequence will be generated by computer using an online randomization generator by a researcher not involved in participant recruitment or outcome assessment. The sequence will be prepared before the start of recruitment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes. After confirming eligibility criteria and obtaining written informed consent, the researcher will open the next envelope in sequence and assign the participant to either the intervention or control group accordingly. Because of the nature of the intervention (virtual reality simulator versus routine face-to-face childbirth preparation), blinding of participants and the main researcher will not be feasible.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2026-04-18, 1405/01/29

Ethics committee reference number

IR.TBZMED.REC.1405.029

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Childbirth preparedness
Timepoint
Baseline (before intervention) and immediately after completion of the training sessions
Method of measurement
Researcher-developed birth preparedness checklist score

Secondary outcomes

1

Description
Childbirth self efficacy
Timepoint
Immediately after completion of the training sessions; and one week after the end of the intervention.
Method of measurement
Childbirth Self Efficacy Inventory

2

Description
Fear of childbirth
Timepoint
Baseline (before intervention); immediately after completion of the training sessions; and one week after the end of the intervention.
Method of measurement
Wijma Questionnaire (W-DEQ)

3

Description
Usability of the virtual reality simulator
Timepoint
Immediately after the first exposure/session (post intervention)
Method of measurement
System Usability Scale

4

Description
Sense of presence
Timepoint
Immediately after the virtual reality intervention session (post-exposure only).
Method of measurement
I group Presence Questionnaire (IPQ)

Intervention groups

1

Description
Intervention group: Pregnant women will receive childbirth preparation training using a 360 degree video based virtual reality simulator. The content includes breathing techniques, relaxation exercises, labor positions, non pharmacological pain management methods, and the supportive role of a birth companion. The intervention is delivered in a supervised clinical setting using a virtual reality headset in a seated position. Each session lasts 15 to 20 minutes.
Category
Early detection

2

Description
Control group: Pregnant women will receive routine face to face childbirth preparation education in the same clinical setting. The education follows national standard guidelines and includes breathing exercises, pelvic movements, labor positions, and non pharmacological pain relief methods.
Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
solmaz ghanbari homayi
Street address
Tabriz, Rahahan Sq
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Fax
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homayisolmaz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Khosro Adibkia
Street address
Central Building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, Iran.
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info@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Solmaz Ghanbari Homaie

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

East Azerbaijan Province, Tabriz, Rahahan Sq, Taleghani hospital

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5197615413

Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Solmaz Ghanbari Homaie

Position

Associate Professor

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified participant level data related to the primary and secondary outcomes of the study, including childbirth preparedness, fear of childbirth, childbirth self

efficacy, usability of the virtual reality simulator, and sense of presence questionnaires. The study protocol, informed consent form, and data collection tools may also be shared upon reasonable request after publication of the study results. All shared data will be anonymized and provided in a way that protects participant confidentiality

When the data will become available and for how long

The study documents and deidentified participant data will be available starting 6 months after publication of the study results and will remain available for 5 years upon reasonable request to the principal investigator.

To whom data/document is available

Qualified researchers, academic investigators, and postgraduate students affiliated with recognized academic or research institutions may request access to deidentified data and study documents for scientific research purposes.

Under which criteria data/document could be used

Data and study documents will be shared upon reasonable request for scientific research, secondary analysis, or academic purposes. Requests will be reviewed by the principal investigator. Shared data must remain deidentified, be used only for approved research purposes, and not be transferred to third parties without permission.

From where data/document is obtainable

Data and study documents will be available upon reasonable request from the Principal Investigator, Nafiseh Mohammadkhani, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran. Requests may be submitted by email to mohammadkhaninafiseh@gmail.com. Postal correspondence may be sent to Miyaneh Azadegan-e Jonubi Street, 17th Alley, No. 50 postal code: 5317644361. The preferred method of contact is email.

What processes are involved for a request to access data/document

Requests to access study data or documents must be submitted via email to the Principal Investigator, including a brief description of the research purpose and proposed analysis. The Principal Investigator will review the request for scientific merit and ethical compliance. If necessary, clarification or additional documentation may be requested. Approved requests will require a data use agreement to ensure confidentiality and appropriate use of deidentified data. After final approval, data will be prepared and shared electronically in a secure format. The entire process is expected to take approximately 2 to 4 weeks depending on the completeness of the request and review time.

Comments